



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Hugh Sharkey and Gary S.
Fanton

Art Unit : 3739
Examiner : David M. Shay

Serial No. : 08/714,987

Filed : September 17, 1996

Title : METHOD AND APPARATUS FOR CONTROLLED CONTRACTION OF SOFT
TISSUE

Mail Stop Appeal Brief - Patents

Commissioner for Patents

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REPLY BRIEF

The Examiner's Answer raised new points with regard to the meaning of "adjacent fluid medium" and the disclosure of Cosman (1984). The Examiner's Answer also raised new points with regard to various dependent claims and whether certain claims rise or fall together.

Pursuant to 37 C.F.R. § 41.41, Appellant responds to these new points raised in the Examiner's Answer.

Adjacent Fluid Medium is Extrastitial

The Examiner's Answer addresses the meaning of the recited "adjacent fluid medium" by commenting on Appellant's description of that term, in part, as follows:

[T]he fluid medium is described a follows: "Fluid medium (gas, liquid, or combination) 30 [may be] flowing as would result from irrigating collagen containing tissue 28 or it may be substantially less dynamic or non-moving. Further[,] fluid medium 30 need only be partially fluid and contain bone, portions of organs or other bodies and the like." This very broad definition clearly reads upon even the interstitial fluid (such as the cell[ul]ar contents and blood that would be released by the cells ruptured on insertion of the probe).

(Answer, page 5, quoting in part Appellant's specification at page 11, lines 13-16). Appellant respectfully disagrees with the conclusion of the Examiner's Answer.

The paragraph from which the Examiner's Answer quotes specifically refers to Figure 3, beginning with "As illustrated in Figure 3" (Appellant's specification, page 11, line 8). Thus, Appellant's description of fluid medium 30 is provided in the context of Figure 3, which explicitly shows that fluid medium 30 is extrastitial to tissue 28, and not interstitial. Further, nothing in the portion quoted by the Examiner's Answer suggests that interstitial fluid is contemplated, but indicates rather that the extrastitial fluid 30 may be "flowing" or "non-moving," and may contain other material such as "bone" and "portions of organs" (Appellant's specification, page 11, lines 13-16).

Cosman et al. (1984) Does not Disclose Sensing Temperature of Extrastitial Fluid

The Examiner's Answer appears to suggest that even if the recited "adjacent fluid medium" does refer to extrastitial fluid, and not to interstitial fluid, Cosman et al. (1984) still discloses "a sensor completely enclosed by the thermally conductive material, and positioned within the thermally conductive material to detect a thermal energy from the selected site and from an adjacent fluid medium" (claim 74; see also claim 82 which includes a similar recitation). Specifically, the Examiner's Answer asserts that "[t]urning first to figure 3, ... if the device of Cosman et al (1984) were placed in the environment and the manner shown therein, it would function just as Appellants' device" (Answer, page 5). Appellant respectfully disagrees.

Figure 3 shows a device placed in surface contact with tissue 28, and able to detect thermal energy from tissue 28 and from adjacent fluid medium 30 (see also Appellant's specification at, e.g., page 12, lines 20-30). In contrast, Cosman et al. (1984) describes a device having a "sharpened tip with a built-in thermocouple sensor" (page 948, 1st column). The tip of the device of Cosman et al. (1984) is described as being "in the tissue [and] absorb[ing] heat from [the tissue]" (page 946, 2nd column). Cosman et al. (1984) does not describe or suggest, at least, that the sensor can detect heat from the tissue if the tip is not inserted into the tissue, as would be the case if the tip were in a surface contact arrangement with the tissue such as that shown in Figure 3 of Appellant's specification. And once the tip is inserted into the tissue, Cosman et al. (1984) does not describe or suggest, at least, that the sensor can detect heat from an adjacent fluid medium.

Accordingly, Cosman et al. (1984) does not describe or suggest, at least, positioning the sensor of the device of Cosman et al. (1984) at a selected site such that the sensor of the device of Cosman et al. (1984) would detect thermal energy from the selected site and the adjacent fluid medium. Furthermore, the mere possibility that the sensor of Cosman et al. (1984) could detect thermal energy from the selected site and the adjacent fluid medium is not a proper basis for inherency, as explained in Appellant's appeal brief at pages 4-5.

"Proximal" Recitation Overlooked

Regarding claims 77, 80, 81, 85, 87, and 88, the Examiner's Answer concludes that "the material between the tissue and the temperature sensor (i.e. electrode material) must be thermally conductive" (Answer, page 7). This conclusion is not responsive to Appellant's appeal brief nor, more importantly, to the claim language. Each of claims 77, 80, 81, 85, 87, and 88 recites that at least a portion of the thermally conductive material is at "a position proximal to the sensor," and the Examiner's Answer does not address these recitations. Further, as stated in Appellant's appeal brief, Cosman et al. (1984) does not describe the claimed conductive material at a position proximal to the sensor (see Appellant's appeal brief, page 5).

"Sensing" Recitation Overlooked

The Examiner's Answer acknowledges that the rejection of claim 90 in the Final Office Action erred in attributing particular disclosure to Makower et al., and reverts to a "rejection based on the obviousness of the re-insertion for treatment purposes" as provided in an Office Action from October 2002 (Answer, page 7). In the October 2002 Office Action, the Examiner states that "[i]t would have been obvious [over Makower et al.] to the artisan of ordinary skill to re-insert the applicator e.g. if subsequent diagnosis determines the further treatment is needed, thus producing a method such as claimed" (October 2002 Office Action, pages 2-3). This obviousness rejection from 2002 was not part of the final office action, contrary to the statement in the Examiner's Answer (Answer, page 7) and contrary to the "Grounds of Rejection" provided in the Examiner's Answer (Answer, pages 4-5). Because the Examiner's Answer is changing the rejection that is on appeal, Appellant provides the following remarks.

Appellant submits that the Examiner has not provided a *prima facie* case of obviousness because, at least, the Examiner has not addressed all of the recitations of claim 90. Claim 90 recites "sensing an elevated composite temperature." As stated in Appellant's appeal brief, neither Makower et al. nor Cosman et al. (1984) describes sensing the temperature of adjacent fluid medium, let alone a composite temperature (see Appellant's appeal brief, page 7).

Further, claim 90 includes several related recitations: (1) "delivering sufficient energy ... causes fluid medium ... to increase in thermal energy," (2) "moving the energy delivery device away ... after delivering sufficient energy," and (3) "moving the energy delivery device back ... and sensing an elevated composite temperature due to the increased thermal energy in the fluid medium" (emphasis added). Thus, the recited "sensing" occurs at a point in time when the increased thermal energy in the fluid medium is still present from the recited delivering of sufficient energy. The Examiner's rejection fails to address, at least, this recitation of "sensing an elevated composite temperature due to the increased thermal energy in the fluid medium." In particular, the Examiner suggests a scenario in which a device is removed from the selected site, then a "subsequent diagnosis" is performed to determine that "further treatment is needed," then the device is "re-insert[ed]" (October 2002 Office Action, pages 2-3). However, the Examiner has provided no argument or contention that the recited "elevated composite temperature" would still be present so as to allow "sensing" of the elevated composite temperature after the removal, diagnosis, and re-insertion.

The Examiner's Answer also asserts that Appellant's challenge of the obviousness rejection is "unreasonable" due to the passage of time (Examiner's Answer, page 7). The Examiner's Answer provides no legal basis for such an assertion. Appellant submits that there is nothing unreasonable about responding to the Examiner's grounds of rejection.

"To Reduce Stray Contractions" Recitation Overlooked

Regarding claim 93, the Examiner's Answer describes the temperature control of Cosman et al. (1984), concluding that the level of energy is reduced (Answer, page 8). However, the Examiner's Answer does not address the reduction of stray contractions in the recitation of "delivering a lower level of energy to reduce stray contractions caused by increased thermal

energy in the fluid medium" (claim 93, emphasis added). As stated in Appellant's appeal brief, Makower et al. and Cosman et al. (1984) do not address adjusting the level of energy due to an effect increased thermal energy in adjacent fluid medium has on the tissue being treated (Appellant's appeal brief, page 7). Accordingly, Appellant submits that the Examiner has not provided a *prima facie* case of obviousness.

Mischaracterization of Claims Rising or Falling Together

The Examiner's Answer states that "claims 89-94 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof" (Answer, page 2). Appellant's disagree. Appellant's appeal brief states that "[n]one of the claims rise and fall together besides those specifically stated herein," and specifically identifies that only (1) "[c]laims 48, 50, 53, 74, 75, 78, 79, 82, 83, and 86 rise and fall together," and (2) "[c]laims 77, 80, 81, 85, 87, and 88 rise and fall together" (Appellant's appeal brief, page 3). Appellant's appeal brief also argues claims 90 and 93 separately in the Argument section (Appellant's appeal brief, page 7).

The Examiner's Answer also appears to state that claims 77, 80, 81, 85, 87, and 88 should rise or fall together with claims 48, 50, 53, 74, 75, 78, 79, 82, 83, and 86 because Appellant's "arguments regarding the patentability of claims 77, 80, 81, 85, 87, and 88 are limited to the assertion that neither Cosman et al (1984) nor any of the references with which it has been combined do not [sic] provide the claimed sensor placement. However, this is also the crux of the argument [put] forth regarding claims 48, 50, 53, 74, 75, 78, 79, 82, 83 and 86" (Answer, pages 2-3). Appellants disagree. Appellants have provided a separate argument for patentability of claims 77, 80, 81, 85, 87, and 88 that addresses the recited locations of the thermally conductive material (that is, the "proximal" recitations), as described above and in Appellant's appeal brief at page 5.

For these reasons, and the reasons stated in Appellant's Appeal Brief, Appellant submits that the final rejection should be reversed.

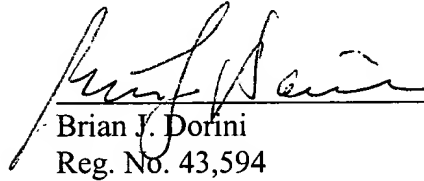
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Respectfully submitted,

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